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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,379	08/02/2006	Tomas J. Ekstrom	5156-0103PUS1	8424

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EXAMINER
EPPS SMITH, JANET L

ART UNIT	PAPER NUMBER
1633	

NOTIFICATION DATE	DELIVERY MODE
03/25/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/588,379	EKSTROM ET AL.	
	Examiner	Art Unit	
	Janet L. Epps-Smith	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-68* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-68* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 2-8, drawn to a pharmaceutical composition comprising at least one compound capable of enhancing gap-junction communication and at least one nucleoside analogue, wherein said enhancing gap-junction is an aromatic organic acid.

Group 2, claim(s) 9, drawn to a pharmaceutical composition comprising at least one compound capable of enhancing gap-junction communication and at least one nucleoside analogue, wherein said enhancing gap-junction is valproic acid.

Group 3, claim(s) 10, drawn to a pharmaceutical composition comprising at least one compound capable of enhancing gap-junction communication and at least one nucleoside analogue, wherein said enhancing gap-junction is splitomicin.

Group 4, claim(s) 11, and 64 drawn to a pharmaceutical composition comprising at least one compound capable of enhancing gap-junction communication and at least one nucleoside analogue, wherein said enhancing gap-junction is butyric acid.

Claim 1, 26-31, 62 and 65-68 link invention groups 1-4.

Group 5, claim(s), 13-18, and 24-25 drawn to a pharmaceutical composition comprising at least one compound capable of enhancing gap-junction communication and at least one nucleoside analogue, further comprising a source of deoxyribonucleoside kinase, wherein the source is a gene therapy vector.

Group 6, claim(s), 19-20, and 24-25 drawn to a pharmaceutical composition comprising at least one compound capable of enhancing gap-junction communication and at least one nucleoside analogue, further comprising a source of deoxyribonucleoside kinase, wherein the source is a protein formulation.

Group 7, claim(s), 21-25 drawn to a pharmaceutical composition comprising at least one compound capable of enhancing gap-junction communication and at least one

nucleoside analogue, further comprising a source of deoxyribonucleoside kinase, wherein the source is a composition of human stem cells, progenitor cells or precursor cells genetically engineered to express a heterologous deoxyribonucleoside kinase.

Claims 1, 12, 26-31, 62-63, and 65-68 link invention groups 5-7.

Group 8, claim(s) 33-42, drawn to a method for treating cancer comprising administering at least one compound capable of increasing gap-junction communication, and at least one nucleoside analogue, further comprising a source of deoxyribonucleoside kinase, wherein the source is a gene therapy vector.

Group 9, claim(s), 43-44 drawn to a method for treating cancer comprising administering at least one compound capable of enhancing gap-junction communication and at least one nucleoside analogue, further comprising a source of deoxyribonucleoside kinase, wherein the source is a composition of human stem or precursor/progenitor cells.

Group 10, claim 46, drawn to a method for treating cancer comprising administering at least one compound capable of increasing gap-junction communication, and at least one nucleoside analogue, wherein said enhancing gap-junction communication is 4-phenylbutyrate, or a pharmaceutically acceptable salt thereof.

Claim 32-35, and 45 link invention groups 8-10.

Group 11, claims 58-61, drawn to a method of augmenting the therapeutic activity of nucleoside analogue based cancer therapy.

The inventions are distinct, each from the other because of the following reasons:

2. The inventions listed as Groups 1-11 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The instant claims are drawn to multiple products and multiple methods.

3. See 37 CFR § 1.475(b)-(d): "[A]n international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the

said process.

(c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.

(d) If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and § 1.476(c).

4. In the instant case, as per CFR § 1.475(d), since the instant claims are drawn to multiple categories of invention since the claims recite multiple patentably distinct products and methods, the instant claims are considered to lack unity of invention.

5. Furthermore, the prior art teaches the technical feature associated with groups 1-11, specifically wherein the claims encompass, pharmaceutical compositions comprising at least one compound capable of increasing gap-junction communication, and at least one nucleoside analogue, wherein said enhancing gap-junction communication is an aromatic acid, and further wherein the composition is used for the treatment of cancer in a patient. See for example Chung et al. (2000) which teaches a method for treating nasopharyngeal carcinoma comprising administering phenylbutyrate and ganciclovir, see abstract. Therefore, since groups 1-11 do not share a special technical feature that makes a contribution over the prior art, the instant groups are considered to lack unity of invention.

6. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

9. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product

are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Smith whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Smith/
Primary Examiner
Art Unit 1633